

What is claimed is:

1. A method for determining an elasticity coefficient of a target, comprising the steps of:  
determining simultaneously two or more critical-angle reflections of an ultrasound wave  
5 from the target using an ultrasound transducer comprising a transmitter and two or more receivers; and  
calculating the elasticity coefficients of the target.
2. The method of claim 1, wherein the target comprises bone.
3. The method of claim 1, wherein the target comprises human bone.
- 10 4. The method of claim 1, wherein the target comprises a human bone from a human being suffering from or suspected of having osteoporosis.
5. The method of claim 1, wherein the target comprises bone from a human being suffering from or suspected of having osteoporosis under treatment with bisphosphonate.
6. The method of claim 1, wherein the detection step is non-invasive.
- 15 7. The method of claim 1, wherein one or more elasticity coefficients are determined from the square of ultrasound velocity as determined from the identified critical angle.
8. The method of claim 1, further comprising the steps of:  
determining a maximum elasticity coefficient and a minimum elasticity coefficient to estimate a degree of target anisotropy; and  
20 using the critical-angle reflection values detected at multiple rotational orientations from the ultrasound transducer fixed at a position normal to a bone surface.
9. The method of claim 2, further comprising the step of determining a maximum elasticity coefficient and a minimum elasticity coefficient to estimate a degree of bone anisotropy.
- 25 10. The method of claim 1, further comprising the step of automating the determination of the normal of the transducer to the target.

11. The method of claim 1, wherein the step of detecting simultaneously is further defined as comprising the simultaneous reception from 2, 4, 8, 16, 24, 36, 48, 64 or 128 receivers.

12. The method of claim 1, further comprising the step of storing the critical-angle values detected in the reflection of an ultrasound wave at two or more receivers that are concentric with a transmitter.

13. The method of claim 1, wherein comprising the steps of:  
storing the detected critical-angle reflections of ultrasound waves at different points in time; and

10 comparing the measurements to track changes in the coefficient of elasticity of the target.

14. The method of claim 1, wherein the step of detecting at two or more angles uses a transducer head comprising at least one transmitter and two or more receivers that detect simultaneously the reflected ultrasound energy from the target, wherein the transmitter and the two or more transducers have a common focal point.

15. The method of claim 1, wherein the transmitter is concave.

16. The method of claim 1, wherein the two or more receivers for part of a concave array in at least two dimensions.

17. The method of claim 1, wherein the transmitter and the two or more receivers are concave and concentric.

18. The method of claim 1, wherein the transmitter is concave and the two or more receivers are concave and the transmitter and the two or more receivers are concentric about a common focal point.

19. The method of claim 1, wherein the receivers are further defined as a receiving array and the array comprises 48 independent receiving transducers that are concentric and concave and share a focal point with the transmitter.

20. The method of claim 4, wherein the human has bone disease, a bone-losing condition other than osteoporosis, or a condition suspected of causing inferior bone strength.

21. The method of claim 5, wherein the treatment of osteoporosis comprises drugs other than bisphosphonate, e.g., an estrogen, an estrogen analog, a parathyroid hormone peptide, a fluoride, a vitamin D, and a calcitonin.

22. The method of claim 5, wherein the treatment is suspected of causing bone loss.

5 23. The method of claim 5, wherein the treatment is suspected of causing bone loss caused by a steroid or anticonvulsant.

24. The method of claim 5, wherein the step of detecting simultaneously two or more critical-angle reflections of an ultrasound wave from the target is taken prior to initiation of bisphosphonate treatment, in order to identify patients with inferior bone quality in  
10 whom bisphosphonate should be used with caution.

25. A method for determining the effect on a coefficient of elasticity of bone from a patient undergoing treatment for osteoporosis, comprising the steps of:

detecting simultaneously at two or more angles the critical-angle reflections of ultrasound waves directed at a bone using an ultrasound transducer with one or more transmitters  
15 and two or more receivers; and

calculating the anisotropy of the bone from the ratio of a maximum elasticity coefficient and a minimum elasticity coefficient, wherein elasticity coefficients are derived as the square of the velocities of an ultrasound waves as determined from the critical angle.

26. The method of claim 25, wherein comprising the steps of:

20 storing a first detected critical-angle reflection of ultrasound waves at two or more receivers prior to, or concurrent with, treatment with a bisphosphonate or derivative thereof;

storing a second detected critical-angle reflection of ultrasound waves at two or more receivers after a period of time; and

25 comparing the first and second measurements to track changes in the elasticity coefficient of the bone during treatment with the bisphosphonate or derivative thereof.

27. The method of claim 25, wherein the step of detecting simultaneously at two or more angles the critical-angle reflection of ultrasound waves directed at a bone using an

ultrasound transducer further comprises measuring a maximum and a minimum elasticity of a cortical and a trabecular region of the bone; and  
estimating the anisotropy of the bone *in vivo*.

28. The method of claim 27, wherein determining the elasticity of cortical bone,  
5 trabecular bone, and anisotropy of a patient's bone is non-invasive.

29. The method of claim 28, wherein the measurement of elasticity is at a heel.

30. The method of claim 28, wherein the step of calculating the anisotropy of the  
bone further comprises determining the maximum and the minimum elasticity coefficient  
of a cortical and a trabecular bone region, wherein the measurements correspond to an  
10 axis of a weight-bearing and a non-weight-bearing bone, respectively.

31. The method of claim 25, wherein the patient has bone disease, a bone-losing  
condition other than osteoporosis, or a condition suspected of causing inferior bone  
strength.

32. The method of claim 26, wherein the treatment of osteoporosis comprises an  
15 estrogen, an estrogen analog, a parathyroid hormone peptide, a fluoride, a vitamin D, and  
a calcitonin.

33. The method of claim 26, wherein the treatment is suspected of causing bone loss  
caused by steroid or anticonvulsant.

34. The method of claim 26, wherein the step of detecting simultaneously two or  
20 more critical-angle reflections of an ultrasound wave from the target is prior to initiation  
of bisphosphonate treatment, in order to identify patients with inferior bone quality in  
whom bisphosphonate should be used with caution.

36. A transducer comprising:  
at least one ultrasound transmitter; and  
25 two or more receivers separated by an angle that form a receiver array and is concentric  
and shares a focal point with the transmitter and, wherein the receiver array detects  
simultaneously the reflected ultrasound energy from a target.

37. The transducer of claim 36, wherein the transmitter is concave in at least two dimensions.

38. The transducer of claim 36, wherein the two or more receivers that form part of a concave array in at least two dimensions.

5 39. The transducer of claim 36, wherein the transmitter and the two or more receivers are concave and concentric.

40. The transducer of claim 36, wherein the transmitter is concave and the two or more receivers are concave and the transmitter and the two or more receivers are concentric about a common focal point.

10 41. The transducer of claim 36, wherein the receivers are further defined as a receiving array and the array comprises 2, 4, 8, 16, 24, 36, 48, 64 or 128 independent receivers.

42. The transducer of claim 36, wherein the array system is comprised of a single transmitter and a 48-element receiver array located in a housing, wherein the receiver  
15 array measures simultaneous the velocity of an ultrasound wave across 120 degrees from a point of examination that is at or about the focal point of the transmitter.

43. The transducer of claim 36, further comprising a housing for the transmitter and the at least two receivers, the housing having at least one opening at or about the focal point of the transmitter and receivers.

20 44. The transducer of claim 36, further comprising:

a housing for the transmitter and the at least two receivers, the housing having at least one opening;

a latex membrane at or about the opening of the housing; and

an ultrasound conductive material within the housing.

25 45. The transducer of claim 44, wherein the ultrasound conductive material comprises water.

46. The transducer of claim 36, further comprising a computer-controlled positioning arm connected to the transducer, wherein movement of the transducer permits accurate positioning of device on a point of examination.

47. The transducer of claim 44, further comprising a pressure detector in communication with the ultrasound conductive material, which detects the increase in pressure within the housing that may break the latex membrane.

48. The transducer of claim 36, further comprising at least one computer connected to transmitter and receivers of the transducer, the computer comprising at least one code segment that gathers one or more reflected spectra from each receiver at each angle, and calculates from the spectra the critical angles for a cortical and a trabecular bone.

49. The transducer of claim 48, wherein the computer further comprises at least one code segment that determines critical-angle velocities, and fits them to a linear-quadratic equation for the determination of at least two principal coefficients of elasticity.

50. A transducer comprising:

at least one ultrasound transmitter; and

a receiver array that is concentric and shares a focal point with the transmitter, wherein the receiver array detects simultaneously the reflected ultrasound energy from a target at multiple angles.

51. The transducer of claim 50, wherein the transmitter is concave in at least two dimensions.

52. The transducer of claim 50, wherein the receiver array comprises a concave array in at least two dimensions.

53. The transducer of claim 50, wherein the receiver array comprises 2, 4, 6, 12, 24, 36 or 48 independent receiving transducers.

54. The transducer of claim 53, wherein the transducer comprises a single transmitter and the receiver array, wherein the receiver array measures simultaneously the velocity of an ultrasound wave across 120 degrees from a point of examination that is at or about the focal point of the transmitter.

55. The transducer of claim 50, further comprising a housing for the transmitter and the receiver array, the housing having at least one opening at, about or adjacent to, the focal point of the transmitter and receiver array.

56. The transducer of claim 50, further comprising:

5 a housing for the transmitter and the at least two receivers, the housing having at least one opening;

a latex membrane at or about the opening of the housing; and

an ultrasound conductive material within the housing.

10 57. The transducer of claim 56, wherein the ultrasound conductive material comprises water.

58. The transducer of claim 50, further comprising a computer-controlled positioning arm connected to the transducer, wherein movement of the transducer permits accurate positioning of device on a point of examination.

15 59. The transducer of claim 50, further comprising a pressure detector positioned to contact the ultrasound conductive material detects when excessive pressure is applied to the latex membrane enclosing ultrasound conductive material within the housing.

60. The transducer of claim 50, further comprising at least one computer connected to the transmitter and the receiver array.

20 61. The transducer of claim 60, wherein the computer comprises at least one code segment that gathers one or more reflected spectra from the receiver array and calculates from the spectra one or more critical angles for a cortical and a trabecular bone.

25 62. The transducer of claim 60, wherein the computer comprises at least one code segment that determines critical angle velocities, and fits the critical angle velocity to a linear-quadratic equation for the determination of at least two principal coefficients of elasticity.

63. A system for measuring bone anisotropy comprising:

a computer-controlled ultrasound critical-angle reflectometry transducer that detects ultrasound velocities at multiple angles simultaneously and automatically;

an articulated arm that permits motion in three-dimensions that supports the ultrasound transducer; and

a computer connected to and capable of receiving a signal from the ultrasound transducer to calculate critical-angle reflectometry data from the ultrasound transducer.

5     64.     The system of claim 63, wherein the computer is connected one or more controllers of the articulated arm that direct the position of the transducer in three dimensions.

65.     The system of claim 63, wherein the transducer measures elasticity coefficients of bone from a patient suffering from or suspected of having osteoporosis.

10     66.     The system of claim 63, wherein the transducer measures the elasticity coefficients of bone from a patient suffering from or suspected of having osteoporosis who was treated with bisphosphonate.

67.     The system of claim 63, wherein the computer determines an elasticity coefficient by comparing the square of the velocity of an ultrasound wave with the intrinsic  
15     orientation of bone at a fixed position using values detected at multiple orientations using the ultrasound transducer.

68.     The system of claim 63, wherein the computer calculates a maximum elasticity coefficient and a minimum elasticity coefficient to estimate a degree of target anisotropy.

69.     The system of claim 63, wherein the computer automates the determination of the  
20     normal of the transducer to the target.

70.     The system of claim 63, wherein computer receives simultaneously receiver data from 2, 4, 8, 16, 24, 36, 48, 64 or 128 different receivers.

71.     The system of claim 63, wherein the computer stores a detected critical-angle reflection value of an ultrasound wave at two or more receivers that are concentric with a  
25     transmitter.

72.     The system of claim 63, wherein the computer stores a value for critical-angle reflection of ultrasound waves at different points in time.



73. The system of claim 63, wherein the computer stores a value for critical-angle reflection of ultrasound waves at different points in time to determine a coefficient of elasticity and tracks changes in the coefficient of elasticity of a target.

74. The system of claim 63, wherein the number of receivers is an odd number  
5 greater than 1.

75. The system of claim 63, wherein the computer determines the effect on an elasticity coefficient of a bone from a patient undergoing therapy for osteoporosis.

76. The system of claim 63, wherein the computer determines the effect on an elasticity coefficient of bone from a patient undergoing therapy for osteoporosis by  
10 storing a first and a second value for the elasticity coefficient of a patient at a first and a second point in time, and calculates a bone anisotropy value from the ratio of a maximum elasticity coefficient and a minimum elasticity coefficient and tracks bone anisotropy over time.

77. The system of claim 63, wherein the computer determines the effect on a  
15 coefficient of elasticity of bone from a patient undergoing bisphosphonate therapy for osteoporosis by storing a first and a second value for an elasticity coefficient of a patient at a first and a second point in time, and calculates a bone anisotropy value from the ratio of a maximum elasticity coefficient and minimum elasticity coefficient and tracks anisotropy over time in order to derive the effect of bisphosphonate treatment on bone  
20 quality.

78. The system of claim 63, wherein the transducer is used to detect the ultrasound critical-angle reflectometry measurement at a heel.

79. The system of claim 63, wherein the computer calculates the anisotropy of the bone further by determining a maximum elasticity coefficient and a minimum elasticity  
25 coefficient of a cortical and a trabecular bone region, wherein the measurements correspond to an axis of a weight-bearing and a non-weight-bearing bone, respectively.

80. The system of claim 65, wherein the human has bone disease, a bone-losing condition other than osteoporosis, or a condition suspected of causing inferior bone strength.

81. The system of claim 66, wherein the treatment of osteoporosis comprises an estrogen, an estrogen analog, a parathyroid hormone peptide, a fluoride, a vitamin D, and a calcitonin.

82. The system of claim 66, wherein the treatment is suspected of causing bone loss.

5 83. The system of claim 66, wherein the treatment is suspected of causing bone loss caused by a steroid or an anticonvulsant.

84. The system of claim 66, wherein the critical-angle reflectometry measurements are made prior to initiation of bisphosphonate treatment, in order to identify patients with inferior bone quality in whom bisphosphonate should be used with caution.

10 85. A method for simultaneously measuring maximum and minimum elasticity coefficients and anisotropy of bone non-invasively *in vivo* in accordance with the method of claim 1.

86. A method for taking simultaneous measurements of maximum and minimum elasticity coefficients and anisotropy of cortical and trabecular bone non-invasively *in vivo* in accordance with the method of claim 25.

87. A method for taking simultaneous measurements of maximum and minimum elasticity coefficients and anisotropy of cortical and trabecular bone non-invasively *in vivo* using the transducer of claim 36.

88. A method for taking simultaneous measurements of maximum and minimum elasticity coefficients and anisotropy of cortical and trabecular bone non-invasively *in vivo* using the transducer of claim 50.

89. A method for taking simultaneous measurements of maximum and minimum elasticity coefficients and anisotropy of cortical and trabecular bone non-invasively *in vivo* using the system of claim 66.